

Amendment and Response

Applicant: Jon Ocel et al.

Serial No.: 10/056,807

Filed: January 25, 2002

Docket No.: M190.134.101

Title: FLUID-ASSISTED ELECTROSURGICAL INSTRUMENT WITH SHAPEABLE ELECTRODE

REMARKS

The following remarks are made in response to the Office Action mailed February 16, 2005. In the Office Action, the claims were rejected as follows: claims 1-4, 7-18, 24-31 and 33-34 were rejected 35 U.S.C. § 103(a) as being unpatentable over Hovda et al., U.S. Patent No. 6,053,172 ("Hovda") in view of Unsworth, U.S. Patent No. 6,520,927 ("Unsworth"). Claims 44-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Unsworth, and further in view Schroepfel, U.S. Patent No. 6,395,038. Claims 1-11, 13-16, and 24-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Unsworth, and further in view Panescu et al., U.S. Patent No. 5,688,267. Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Unsworth, and further in view of Moaddeb et al., U.S. Patent No. 6,405,078. Claims 22 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Unsworth, and further in view of Knoepfler, U.S. Patent No. 5,300,087. Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Unsworth, and further in view of Knoepfler in view of Borst et al., U.S. Patent No. 6,328,688.

In addition, the Examiner's comments in paragraph one of page 10 are noted with appreciation.

With this Response, claim 53 is newly presented. Claims 1-53 remain pending in the application and are presented for consideration and allowance.

Claim Rejections under 35 U.S.C. § 103

Claims 1-4, 7-18, 24-31, and 33-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Unsworth. It is respectfully submitted that a *prima facie* case of obviousness cannot be established based upon these references, such that the rejections to these claims must be withdrawn. In particular, the Office Action takes the position at page 5 that Hovda does not expressly disclose the use of Nitinol, but Unsworth expressly discloses a shaft made of Nitinol. Applicant respectfully disagrees as Unsworth is directed to retractable catheter needles.

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To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify or combine the reference teachings. Second, there must exist a reasonable expectation of success. Third, the references must teach or suggest all of the claim limitations. MPEP 2143.

Each of pending independent claims 1, 24, and 39 require a shaft that is adapted to be transitionable from a straight state to a first bent state, where the shaft independently maintains distinct shapes in the straight state and the first bent state.

First, Applicant maintains that Hovda teaches a rigid shaft having a specifically designed bend, such that the cited references fail to teach or suggest all of the claim limitations. Hovda teaches in column 16, lines 55-67 an electrosurgical probe 90 including a shaft 100, a handle 204 coupled to a proximal end of the shaft 100, and an electrode support member 102 coupled to the distal end of the shaft 100. Hovda teaches the shaft 100 preferably includes a bend 101 that allows the distal section of shaft 100 to be offset from the proximal section and handle 204. Hovda teaches that this offset facilitates procedures that require an endoscope. *See* Figures 2-5.

Alternately, Hovda teaches a flexible shaft including a generally rigid external tube. Support for this assertion can be found at column 11, lines 5-15 where Hovda teaches flexible shafts are combined with generally rigid external tubes for mechanical support. In lines 8-11, Hovda teaches that flexible shafts may be combined with pole wires, shape memory actuators, and other known mechanisms for affecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. Thus, if the shaft 100 taught in Hovda is flexible at all, it is at the distal end.

To this end, Hovda teaches at column 11, lines 30-39 shafts that have a distal bend accommodate the bend in the patient's throat, or alternately, the shaft 100 may be a rigid shaft having a specifically design bend to correspond with the geometry of the mouth and throat, or the shaft may have a flexible distal end. Therefore, based upon a facial reading of Hovda, it is respectfully submitted that Hovda teaches either a rigid shaft having a specifically designed bend, or a shaft that can include a flexible distal end, such that Hovda fails to teach or suggest a shaft that is adapted to be transitionable from a straight state to a first bent state, where the shaft

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independently maintains distinct shapes in the straight state and the first bent state, as required by all claims of the pending invention.

Moreover, reference is made to Hovda at column 17, lines 52-64 where Hovda teaches the distal portion of the shaft 100 comprises a flexible material, and directs that a more complete description of this embodiment can be found in National Phase Serial No. PCT/US94/05168 (WO 94/26228). Incorporating the teaching of International Publication No. WO 94/26228 at page 19, lines 1-12 to Hovda, Hovda teaches a tubular member 56 composed of a material selected from titanium or its alloys, or nickel or its alloys. In lines 4-11, Hovda teaches the electrically conductive tubular member 56 will preferably be composed of the same metal or alloy that forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50.

The teaching of International Publication No. WO 94/26228 at page 19, lines 1-12 contradicts the position taken in the Office Action at page 5 of the Office Action mailed February 16, 2005 where it is asserted that Hovda teaches a shaft adapted to be transitionable from a straight state to a first bend state. Hovda has no such teaching. Moreover, it is respectfully submitted that the Hovda teaching related to a material selection for the shaft 100 is limited to materials selected for corrosion resistance alone, and no other purpose.

Second, there is no suggestion or motivation to combine the cited references because Unsworth is directed to retractable catheter needles, and Hovda is directed to rigid electrosurgical shafts useful in sinus surgery. Thus, combining Hovda and Unsworth does not result in a shaft made of Nitinol.

Unsworth teaches at column 6, lines 60-65 a catheter 5 that is detachably attached at its proximal end to a stationary case of a linear drive 3, and including a needle 4 within a sheath 10 (Unsworth teaches sheath 10 is not shown in Fig. 1 for diagrammatic clarity). Unsworth teaches at column 3, lines 25-33 a catheter delivered to the heart and having a distal needle end that injects conducting material into the heart tissue. Unsworth teaches a long syringe needle that extends out of a hole near the distal end of the catheter, where the distal end of the catheter

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needle can be straight or hooked, depending upon requirements of the procedure. In this regard, Unsworth teaches that if the needle is straight, it simply exits out of the distal end of the catheter. Alternately, Unsworth teaches if the needle is hooked, it can be made of superlastic Nitinol that permits the needle to be straightened within the catheter, but rebound into a curved shape as it exits a hole in the side of the catheter. *See* Unsworth at Figure 2.

Thus, it is respectfully submitted that Unsworth teaches a pre-tensioned needle 4 that is constrained by the sheath 10 of the catheter when the needle 4 is in a retracted state. When the needle 4 is extended out of the hole near the distal end of the catheter (FIG. 2), the superlastic Nitinol needle is unrestrained and can freely flex into its pre-tensioned (i.e., hooked) state. Consequently, Unsworth teaches a superlastic Nitinol needle that is wholly inapplicable to shafts of electrosurgical devices.

Moreover, Unsworth teaches at column 4, lines 28-32 that the needle must be somewhat loose in the lumen of the catheter to permit movement. It is respectfully submitted that such a needle would be unsuitable as an electrically insulated conductive electrode. In particular, needles that are “somewhat loose in the lumen of the catheter” would be susceptible to electrically shorting out. Thus, the needle in Unsworth teaches away from an elongated rigid shaft useful in sinus surgery, otherwise taught as beneficial by Hovda.

There is no suggestion or motivation to combine the Hovda reference with the Unsworth reference. Even if the Hovda reference were combined with the Unsworth reference, the purported combination still would not teach or suggest a shaft that is adapted to be transitionable from a straight state to a first bend state, the shaft independently maintaining distinct shapes in the straight state and the first bent state, as required by independent claims 1, 24, and 39.

Based upon the above reasoning, a *prima facie* case of obviousness cannot be established based upon Hovda in view of Unsworth. It is respectfully submitted that independent claims 1, 24, and 39 recite patentable subject matter that is not taught or suggested by the cited references. In addition, claims 2-23, 25-38, and 40-52 depend, respectively, from independent claims 1, 24, and 39. Since the independent claims are believed to be non-obvious under the cited references, then the dependent claims must also non-obvious. MPEP 2143.03.

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The Examiner's guidance at page 10 of the Office Action mailed February 16, 2005 is noted with appreciation. With this in mind, claim 53 is newly present to particularly point out and distinctly claim subject matter not taught or suggested by the cited references. Newly presented claim 53 recites a specific structural element employing nouns (i.e., "a shaft," "a first shape," and "a second shape"). In this regard, newly presented independent claim 53 provides: An electrosurgical instrument comprising an elongated shaft defining a proximal section, a distal section, and an internal lumen extending from the proximal section, wherein . . . an entirety of the shaft is transitionable from: a first shape, to a second shape different from the first shape, the shaft independently maintaining the second shape. Support for this language can be located throughout the Specification, and in particular, at page 11, line 25 to page 12, line 20, and FIGS. 5A-5C.

It is respectfully submitted that none of the cited references teach or suggest an entirety of a shaft is transitionable from: a first shape, to a second shape different from the first shape, the shaft independently maintaining the second shape, as required by newly presented independent claim 53. In particular, it is noted that Hovda fails to teach or suggest an entirety of a shaft transitionable from: a first shape, to a second shape different from the first shape, the shaft independently maintaining the second shape.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-53 recite patentable subject matter, are in form for allowance, and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-53 is respectfully requested.

Applicant authorizes the Commissioner for Patents to charge Deposit Account No. 50-0471 in the amount of \$250 for an additional claims, as set forth under 37 C.F.R. § 1.16(h), and in the amount of \$1500 for the Petition to Revive – Unintentional, as set forth under 37 C.F.R. § 1.17(m).

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The Examiner is invited to telephone the Applicant's representative at the below listed number to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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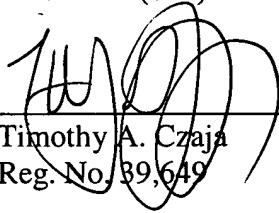
Respectfully submitted,

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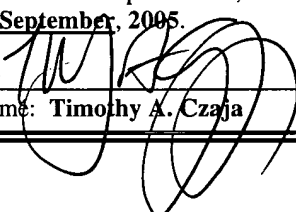
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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 20th day of September, 2005.

By 

Name: Timothy A. Czaja